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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,836	03/15/2006	Jialin Sun	09548.1019USWO	3476

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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
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EXAMINER

GUSSOW, ANNE

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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02/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/571,836	Applicant(s) SUN, JIALIN	
	Examiner Anne M. Gussow	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,12-16,21 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) 27-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,12-16,21 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/15/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 2 and 21 have been amended.
Claims 11 and 22 have been cancelled.
Claims 27-30 remain withdrawn.
2. Claims 1, 2, 12-16, 21, and 23-26 are under examination.

Information Disclosure Statement

3. Applicant has noted that the IDS filed March 15, 2006 was not completely initialed as considered by the examiner. A completely initialed copy of the IDS has been included with the mailing of this Office Action.

Objections Withdrawn

4. The objections to the specification have been withdrawn in view of applicant's amendment to the specification.

Rejections Withdrawn

5. The rejection of claims 2, 11, and 21-26 under 35 U.S.C. 112, first paragraph, as lacking enablement is withdrawn in view of applicant's amendment to the claims.

Rejections Maintained

6. The rejection of claims 1, 2, and 12 under 35 U.S.C. 102(b) as being anticipated by Wahlsten, et al. is maintained.

The response filed November 27, 2007 has been carefully considered but is deemed not to be persuasive. The response states that Wahlsten et al. discloses that crystallographic studies have demonstrated that residues within the TSST1 N-terminal domain directly, interact with MHC II molecules, and mutation analyses of TSST1 have residues critical for its superantigenic activity to the C-terminal domain. Further, when expressed as a recombinant protein, the TSST1 C- terminal residues 88-194 do not bind to MHC II molecules yet retain superantigenic activity. See page 6762, left column, lines 14-20 of the reference. In fact, such binding between TSST1 and MI-IC II molecules is not necessary for TSST1 to be used as an anti-cancer medicine. Thus, the reference does not satisfy an interaction of fusion protein of superantigen and a tumor specific ligand as claimed, namely a ligand that stimulates cancer cell growth and corresponds to receptors overexpressed by cancer cells, or a screened peptide that is affinitive to or antagonist to cancer cell receptors, or a peptide that directly interacts with cancer cell surface (see response pages 7-8).

In response to this argument, the interaction of TSST1 with MHCII molecules did stimulate an anti-cancer immune response as shown in Figure 5 (page 6765). If the interaction of TSST1 with MHCII molecules on normal cells induced an immune response, the control animals in the in vivo studies would have responded to the construct. Additionally, the proto-oncogene erb-B-2 would only be present on cancer cells and the claim recites a ligand that stimulates cancer cell growth or is

overexpressed by cancer cells. Erb-B2 expressed in cancer cells and therefore meets the limitations of the claims.

Therefore, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

7. The rejection of claims 1, 2, 12-16, 21, and 23-26 under 35 U.S.C. 103(a) as being unpatentable over Wahlsten, et al. in view of Chandler, et al. is maintained.

The response filed November 27, 2007 has been carefully considered but is deemed not to be persuasive. The response states that Chandler et al. discloses a fusion protein with toxin protein SAP and a ligand. However, SAP is not a superantigen, and the reference merely describes a fusion protein that may include a heparin-binding epidermal growth factor (HB-EGF) (see response pages 9-10).

In response to this argument, the reference of Chandler et al. was cited in the rejection as providing the tumor cell ligand HB-EGF in a fusion construct. Wahlsten, et al. teach the superantigen in a fusion construct. The state of the art in recombinant protein technology is such that one of ordinary skill in the art would be able to exchange one portion of a fusion construct with another similar portion of a different fusion construct with a reasonable expectation of success. Thus, exchanging the SAP in the construct of Chandler with the superantigen of Wahlsten would have been routine in the art.

Therefore, after a fresh consideration of the claims and the evidence provided the rejection is maintained.

Conclusion

8. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

January 30, 2008

/Larry R. Helms/
Supervisory Patent Examiner